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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/760,085 | 01/12/2001 | Jaap Goudsmit | 9250-28CT | 3169 |

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EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,085

Applicant(s)

GOUDSMIT ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21 and 28-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 and 28-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

Art Unit: 1637

Response to Amendment

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

1. The amendment filed 6/26/2002 has been entered.
2. The rejection of claims 16-21 and 28-37 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment and argument.
3. The rejection of claims 16-21, 25-26 and 29-31 under 35 U.S.C. 103(a) over Boom et al. is withdrawn because of the argument.
4. Claims 32-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al (5,043,272) in view of Mullis et al. (4,965,188) and Sambrook et al. (Molecular cloning, second edition, pg. 8.11-8.17).

Applicants argue that Hartley et al. fails to provide teachings for a primer having a random hybridization sequence and an amplification motif and Hartley et al also do not teach that the amplification motif is a specific sequence that may be utilized in further amplification steps. However, based upon the definition of the amplification motif as defined in the specification and explained in page 7, any nucleic acid primer will have amplification motif and any amplified nucleic acid sequence will be further amplified by a primer which binds to the amplification

Art Unit: 1637

motif. Thus, Applicant's arguments filed 6/26/2002 have been fully considered but they are not persuasive. The rejection is maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-21, 28-31 and 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 16-21, 28-31 and 38-44 are vague and indefinite because of the language “preferentially” in claims 16, 28, 38 and 44. It is unclear whether or not the double stranded nucleic acid binds to the solid phase. Clarification is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16-21, 28-31 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastian et al. (WO 95/21849 (US 6,180,778 used herein as translation)).

Art Unit: 1637

Bastian et al. disclose a method of separating nucleic acid mixture into their double stranded and single stranded fraction. All nucleic acids are simultaneously adsorbed in a mineral substrate, then separated by fractional elution into double stranded and single stranded nucleic acids, or double stranded and single stranded nucleic acid of a sample are selectively adsorbed in a mineral substrate (See the Abstract). The double stranded nucleic acid predominantly binds to the first mineral support and after optionally performed washing steps, can be eluted under conditions for low ionic strength or with water (See column 3, lines 23-28). The non-adsorbed single-stranded nucleic acid collected are subsequently adjusted and can be adsorbed to a second mineral support and become eluted under conditions of low ionic strength or with water (column 3, lines 30-36). The treatment condition contains a chaotropic substance (See column 4, lines 12-16). The mineral support consists of porous or non-porous metal oxides, silica gel or glass (See column 6, lines 6-21). The particle size is 0.1 μm to 1000 μm (See column 6, lines 6-12). For binding double stranded nucleic acid to mineral supports, the solution contains guanidinium thiocyanate with concentration 1 to 8 M and EDTA with the concentration from 5 mM to 200mM (See column 6, lines 49-58). Centrifuge is involved for pelletizing the silica material (See column 8, lines 53-54). Magnesium chloride, in concentration of from 0.1 to 10M may also be in combination for lysing or binding the sources containing nucleic acids (See column 5, lines 61-67 and column 15, claims 11-14). The complexes comprise alkaline earth metal ions bound

Art Unit: 1637

to EDTA (See column 16, claim 22). Thus, the teachings of Bastian et al. anticipate the limitations of claims 16-21, 28-31 and 38-44.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 29, 2002


GARY BENZION, PHD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600